from a process comprising precipitating fibrinogen from a sample of non-human, mammalian blood plasma with polyethylene glycol 1000 and reprecipitating said fibrinogen with glycine, wherein precipitation of said fibrinogen with polyethylene glycol is performed only once, such that at least about 90% of the fibrinogen present in said sample is recovered, wherein said recovered fibrinogen polymerizes when provided in solution at said site at a therapeutically effective fibrinogen concentration of about 10 mg/ml thereof or less, to a fibrin network having therapeutically effective strength, wherein said therapeutically effective fibrinogen concentration at said site is about 10 mg/ml or less, and said composition further comprising a sufficient amount of one or more physiologically-compatible solutes such that said composition, if formulated as a lyophilized material, can be reconstituted therefrom at room temperature in sterile water for injection in about 30 minutes or less, at about 25 mg/ml of said fibrinogen; wherein about 95%, or greater, of total protein present in said composition is fibrinogen.

2. (Amended) A therapeutic composition effective on contact with thrombin at a site of treatment in a patient as a tissue adhesive, hemostat or sealant, said composition comprising non-autologous, non-single donor mammalian, clottable fibrinogen recovered from a process comprising precipitating fibrinogen from a sample of non-human, mammalian blood plasma with polyethylene glycol 1000 and reprecipitating said fibrinogen with glycine, wherein precipitation of said fibrinogen with polyethylene glycol is performed only once, such that at least about 90% of the fibrinogen present in said sample is recovered, wherein said recovered fibrinogen polymerizes when provided in solution at said site at a

therapeutically effective fibrinogen concentration of about 30 mg/ml thereof or less, to a fibrin network having therapeutically effective strength,

wherein said therapeutically effective fibrinogen concentration at said site is about 30 mg/ml or less,

wherein said composition contains less than about 30% (w/w), based on total protein mass present therein, of proteins other than fibrinogen, and said composition further comprises a sufficient amount of one or more low molecular weight physiologically-compatible solutes such that said composition, if formulated as a lyophilized material, can be reconstituted therefrom at room temperature in sterile water for injection in about 30 minutes or less, at about 25 mg/ml of said fibrinogen.

B1

13. (Amended) A reactive therapeutic composition effective on contact at a site of treatment in a patient as a tissue adhesive, hemostat or sealant, said composition comprising, per milliliter thereof, between about 0.05 and about 500 NIH units of thrombin and also, per milliliter, between about 5 and about 30 mg of a fibrinogen composition wherein clottable fibrinogen is recovered from a process comprising precipitating fibrinogen from a sample of non-human, mammalian blood plasma with polyethylene glycol 1000 and reprecipitating said fibrinogen with glycine, wherein precipitation of said fibrinogen with polyethylene glycol is performed only once, such that at least about 90% of the fibrinogen present in said sample is recovered, said recovered fibrinogen polymerizes to a fibrin network having therapeutically effective strength, when present at said site at a therapeutically effective fibrinogen concentration of about 30 mg/ml or less, wherein said

B2

therapeutically effective fibrinogen concentration at said site is about 30 mg/ml or less; wherein about 95%, or greater, of total protein present in said fibrinogen composition is fibrinogen.

E2

Cancel Claim 26.

38. (New) The composition of Claim 1 wherein said therapeutically effective fibrinogen concentration at said site is about 10 mg/ml.

39. (New) The composition of Claim 2 wherein said therapeutically effective fibrinogen concentration at said site is about 30 mg/ml.

E3

40. (New) The composition of Claim 13 wherein said therapeutically effective fibrinogen concentration at said site is about 30 mg/ml.

41. (New) The composition of Claim 1 wherein said therapeutically effective fibrinogen concentration at said site is between about 5 mg/ml to about 10 mg/ml.

Remarks

Applicants respectfully request reconsideration of the subject application in view of the preceding amendments and for the following reasons.